IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/619,380	Confirmation No.:	5428
Applicant:	Whitaker et al.	Filed:	July 14, 2003
Art Unit:	3735	Examiner:	Robert L. Nasser
Docket No.:	281-398.01	Customer No.:	44,331

TITLE: MOTION MANAGEMENT IN A FAST BLOOD PRESSURE MEASUREMENT DEVICE

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION BY TY WHITAKER AND JOHN LANE UNDER 37 C.F.R. 1.132

We, Ty Whitaker and John Lane, hereby declare as follows:

1. We are the co-inventors of the subject matter of all of the claims of the above-identified patent application. We have reviewed independent claims 1 and 27 as submitted contemporaneously herewith.

2. We make this declaration to establish patentability of the subject matter of independent claims 1 and 27 (and of all claims depending therefrom) over the prior art cited in the Office Action mailed from the United States Patent and Trademark Office on December 15, 2006, including U.S. Patent Nos. 5,759,157, 6,405,076, 4,870,973, and 4,592,365.

3. We attach as Exhibit 1 true copies of pages 7, 34, 35, 37, 41, 42, 46, and 47 and the front cover and the title page of the document entitled "Manual, electronic, or automated sphygmomanometers" issued by the Association for the Advancement of Medical Instrumentation as an American National Standard on October 28, 2002 (hereinafter "the Manual"). The filing date of the present application is July 14, 2003.

4. We additionally make reference to US Patent No. 4,860,759, the entire disclosure of which was incorporated by reference into the present application.

5. The Manual at page 7, paragraph 4.5.2.2 Valve/cuff exhaust rate, recites: "The valve shall be adjustable and shall allow pressure reduction to be controlled and maintained at a rate between **2 mmHg/s and 3 mmHg/s**, from initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg." (emphasis added)

6. The Manual at page 34, paragraph A.4.5.2 Manually adjustable valve, and continuing on to page 35, recites:

   The recommended rate of pressure release established by the American Heart Association is 2 mmHg/s to 3 mmHg/s (AHA, 1981). To ensure that the valve can control this rate, the maximum valve leakage should not exceed one-half (1 mmHg/s) of the minimum acceptable rate, as determined in a total system under operating conditions. The volume of the smallest cuff in normal use (excluding the neonatal cuff) is approximately 80 cm^3. The leakage should be measured at 3 pressures throughout the range to verify proper functioning of the check valve within the adjustable valve, particularly at the lower pressures. (emphasis added)

7. The Manual at page 37, paragraph A.4.7 Requirements for system leakage, recites:

   For proper and accurate performance, the leakage rate of the sphygmomanometer system as a whole should be low enough to permit the system to meet the requirements for accuracy and repeatability. **The recommended rate of pressure release established by the AHA is 2 mmHg/s to 3 mmHg/s**. This rate should be controllable by a valve. These criteria can be satisfied if the leakage rate remains below 1 mmHg/s for the entire system. (emphasis added)

8. The Manual at page 41, paragraph B.3 Procedure, subparagraph 3), recites:

   3) The cuff should then be inflated to a pressure about 30 mmHg higher than the previously recorded occluding pressure, and the bleed valve should be opened to allow deflation at a rate of 2 mmHg to 4 mmHg per heartbeat or 3 **mmHg/s**. For automatic devices which do not allow for deflation rates in this range, it might not be possible to perform same-limb measurements simultaneously with cuff/bladder manual auscultation. In such cases, same-limb sequential measurements are preferable to contralateral simultaneous measurements. The manufacturer should describe the method used for appropriate testing to validate the automated device against manual sphygmomanometry.

   NOTE—Check that upon opening the valve at the upper pressure range, the initial escape does not exceed the above
   deflation rate.

   The valve should be manipulated in such a manner as to continue a linear deflation rate of 2 mmHg to 4 mmHg per heartbeat throughout the measurement period. (As the pressure in the cuff decreases, the valve opening should be changed to ensure this linear rate.)

Applicants note for the record that the rate of 3 mmHg/s is equated to 2 mmHg to 4 mmHg per heartbeat. Since heartbeat rates are hardly uniform, Applicants respectfully submit that any measurement stated in units of "per heartbeat" are not informative.

9. The Manual at page 42, paragraph B.4 Major sources of error, subparagraph Rapid cuff deflation, recites:

> As an example of the problem associated with rapid cuff deflation, assume that a patient's systolic pressure is actually 149 mmHg at a given time and that the heart rate is 60 beats/min. Below are pressure recordings, by two hypothetical operators, that illustrate how the cuff deflation rate can contribute to measurement error:
>
> | | | |
> |---|---|---|
> | Deflation rate per second: | 10 mmHg | 3 mmHg |
> | Cuff pressure 150 mmHg: | No K sound | No K sound |
> | First K sound produced: | 140 mmHg | 147 mmHg |
>
> The first operator, using a 10 mmHg/s deflation rate, recorded a systolic pressure of 140 mmHg (9 mmHg below the actual pressure of 149 mmHg); the second operator, using a correct deflation rate (3 mmHg/s), recorded a systolic pressure of 147 mmHg (2 mmHg below actual).
>
> Measurements made from reference sphygmomanometers should be made to the nearest 1 mmHg. This is intended to limit small differences between test and reference methods on account of conventional rounding to the nearest 2 mmHg and allow controlled deflation at 3 mmHg/s or per heartbeat. Automated devices typically measure to the nearest 1 mmHg.

Applicants note for the record that the passage indicates that a deflation rate of 10 mmHg/s results in an erroneous reading, and in fact should not be used, according to the Manual.

10. The Manual at page 46, paragraph C.3 Data collection, and continuing un to page 47, recites:

> The most important aspect of data collection is the specification of the intra-arterial pressure during a determination. The measurement obtained from the noninvasive device is subtracted from the intra-arterial measurement to obtain the error for that particular determination. One method of specifying the intra-arterial pressure and computing the error is to obtain from a multichannel strip-chart recorder or computerized system the actual waveforms of the systolic and diastolic pressures at the instant measured by the noninvasive

device. The difference between the intra-arterial pressure recorded and the noninvasive measurement is then calculated. This is only possible if synchronized recordings have been obtained. Another method is to specifically time the period of measurement of the noninvasive device and note this with an event marker on the recording for the intra-arterial pressure. At 3 mmHg/s cuff deflation, the measurement of blood pressure by the noninvasive device ordinarily takes 45 s to 60 s. The intra-arterial beats from the first 15 s of cuff deflation can be averaged to obtain the reference value for systolic pressure, and the last 15 s of cuff deflation can be averaged to obtain the reference value for diastolic pressure. The error of this method has been calculated to be 0.2 ± 3 mmHg for diastolic and 0.6 ± 2 mmHg for systolic. This method is appropriate if the automated device uses markers for systolic and diastpressure that are independent of the mean pressure. (emphasis added)

11. As taught in U.S. Patent No. 5,759,157 to Harada, at column 5, lines 43-48, and at column 6, lines 24-29, inflation and deflation rates of 2 to 3 mmHg/sec are used during the period when blood pressure measurements are made.

12. As taught in U.S. Patent No. 4,860,759, a common rate of deflation of a blood pressure cuff during a measurement of blood pressure is 3 millimeters of mercury (3 mm of Hg) per second.

13. We respectfully submit that the evidence adduced herein shows that the conventional or accepted rate of inflation or of deflation of a blood pressure cuff during a blood pressure measurement interval is 2 mmHg/s to 3 mmHg/s.

14. All statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true. These statements are made with the knowledge that willful false statements and the like, so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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> device. The difference between the intra-arterial pressure recorded and the noninvasive measurement is then calculated. This is only possible if synchronized recordings have been obtained. Another method is to specifically time the period of measurement of the noninvasive device and note this with an event marker on the recording for the intra-arterial pressure. At 3 **mmHg/s** cuff deflation, the measurement of blood pressure by the noninvasive device ordinarily takes 45 s to 60 s. The intra-arterial beats from the first 15 s of cuff deflation can be averaged to obtain the reference value for systolic pressure, and the last 15 s of cuff deflation can be averaged to obtain the reference value for diastolic pressure. The error of this method has been calculated to be 0.2 ± 3 mmHg for diastolic and 0.6 ± 2 mmHg for systolic. This method is appropriate if the automated device uses markers for systolic and diastpressure that are independent of the mean pressure. (emphasis added)

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